

ATTACHMENT B

REMARKS

By the present amendment, additional amendments have been made to the claims to further point out the differences between the present invention and the prior art. For reasons as stated below, the invention as presently claimed is not disclosed or made obvious by the prior art cited by the Examiner, and withdrawal of the rejections and allowance of the claims in their present form is respectfully requested.

In the present amendment, the one independent claim of the patent, Claim 16, has been amended in such a way as to further emphasize the substantial differences between the present claims and the cited prior art. In particular, as set forth in the specification of the present application, the liquid test specimen or sample is directed through openings 51 in the test card at the location wherein it will directly contact the exposed sample receiving portion of the test strip directly beneath the opening. This embodiment is directly disclosed in the specification, e.g., page 11, bottom paragraph, wherein the test strip is described as having pertinent test and sample portions "exposed through openings." In Figs. 9-11, as described in pages 11-12 of the specification, this embodiment is shown wherein sample openings 51 are provided through which the liquid test specimen is able to contact the exposed portion of the test strips that are directly beneath said openings. As also shown in Fig. 9, for example, the bottom portion of the test card surrounds and blocks the lower end of the test strips, and thus the specification clearly defines a test card system wherein the fluid does not contact the test strips through an exposed edge, but instead contacts it directly on the exposed surface of the strip through openings 51. For reasons as expressed below, there are no references cited by the Examiner which disclose such a structure, and

accordingly no combination of references can be made by which such a structure would become obvious.

In the Official Action, the Examiner rejected the claims under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention. This rejection has become moot by virtue of the present claims which amend the language of the claims and thus do not include the language objected to by the Examiner. However, any argument by the Examiner that there is any lack of disclosure with regard to the test strips of the claimed invention is misplaced. Indeed, the present disclosure adequately describes the general form of a test strip, namely a membrane strip which onto which a drug conjugate may be immobilized so that an identifying reagent, such as a colloidal gold antibody complex may travel along with the urine sample by capillary action. See, e.g., page 13 of the specification. Such test strips are conventional and well known in the art, and as the Examiner himself recognized (see page 4 of the Official Action), Applicants provided reference to actual test strips that were being commercially utilized at the time, see specification at the bottom of page 8 and top of page 9. Moreover, the fact that such tests strips were known is shown by other patent references which describe these strips in much the same manner as the present application. See, e.g., US Pat. App. Pub. 2005/0009203, e.g., paragraph [0016]. In the present application, the test strips were conventional and thus are adequately disclosed. See Hybritech Incorporated v. Monoclonal Antibodies, Inc., 231 USPQ 81, 94 (Fed. Cir. 1986) (a patent specification need not teach what is well known in the art).

Even further, the precise nature of the test strips and how they are located in the test card make it clear that the strip receives the liquid test specimen directly through

opening 51 and not at an edge since the bottom of test card 44 surrounds the bottom end of the test strips and thus does not permit the test specimen to contact the test strip at its lower edge. One reading Applicants' specification is clearly shown that the liquid test sample is directed onto the test strip at the sample portion exposed underneath opening 51 and will move by capillary action so that the fluid will reach the portion of the test strip exposed directly underneath the openings 50 wherein the results of the test will be revealed. As reflected in the present specification, there are numerous brands of test strips that are known to accomplish this purpose, such as the commercial brands disclosed in Applicants' specification, and thus one skilled in the art would be readily able to prepare the test card as described in the specification with any suitable test strip that will accomplish that purpose, namely receive a sample at a sample receiving portion and have the sample move by capillary action up the strip to contact identifying reagents so that the results of the tests will be revealed at a test opening up the strip. The Examiner's suggestions that the present specification discloses any other type of system is thus directly contradicted by the specification and drawings of the present application.

In the Official Action, the Examiner rejected Claims 16 and 19 as being unpatentable over May et al. PCT application WO 88/08534 in view of Sun et al. (US 5,238,652), and rejected Claims 16-19 as being unpatentable over May et al. in view of Sun et al., and further in view of Boger et al. US 4,518,565, These rejections, insofar as applied to the claims as amended, are respectfully traversed for the reasons that follow.

As indicated in Applicants' specification, the present claims are directed to a drug of abuse immunoassay test card wherein the liquid test specimen directly contacts the sample portion of the test strip which is exposed underneath the opening for the sample

portion on the test strip which then more quickly and accurately begins the process by which the sample moves up the strip via capillary action so that drugs in the test specimen can be detected. This differs from the prior art cited by the Examiner wherein no immunoassay test card is shown which discloses any such system. Accordingly, although the Examiner asserts that Applicants are only attacking the references "individually", it is in fact the case that since none of the references show all of the elements of the present claims, and indeed the Examiner's comments confirm this, there is nothing that can be combined in the first place by which one skilled in the art would derive the present invention

In particular, as the Examiner seems to recognize, the May reference does not disclose a device in which the system of the present claims, namely one wherein there is an opening directly above an exposed surface of an immunoassay test strip through which a liquid test sample goes to directly contact a sample receiving portion of the test strip so as to begin the process whereby the sample will wick up the test strip via capillary action and ultimately allow detection of a drug in the sample at an opening at the test portion of the immunoassay test strip. In short, there is simply no such device shown in the May reference, and in each case as shown in the drawing figures, there is simply no occasion wherein there is an exposed opening of the sample receiving portion of the test strip wherein the fluid sample is directly contacted. To the contrary, in all of the different embodiments, there is not a single one shown wherein such an opening directly over an exposed part of the sample receiving portion of the test strip is shown. For example, the embodiment of Figs 1-5 and 13 have an opening only at the end; the embodiments of Figs. 6-7 have a receptacle 202 which is not directly above the test strip; the embodiment of Figs. 8-9 have openings (508-509) only for visualizing the test

results; and the embodiment of Figs. 11-12 have an opening 601 which is not directly above the test strip 606, and thus test strip 606 cannot in any way have any portion below the opening 601, much less the sample receiving portion as set forth in Applicants' claims.

Moreover, there is no structure in the Sun et al. patent which has such a structure, either. In fact, the Examiner's previous official actions only used the combination of Sun et al. to show that "Sun et al. teach that test strips, which may be configured in a parallel arrangement, for the determination of at least five drug of abuse analytes in a single device is preferred." See Official Action of June 20, 2005. Sun does **not** teach or suggest in any manner the specific structure of the present claims, namely a test card which contains immunoassay test strips wherein the test strips are positioned inside the test cards in such a manner that the liquid test specimen directly contacts the sample receiving portion of the test strips which immediately starts the lateral flow of the specimen up the strip to the test portion via capillary action. Sun does not provide, nor does the Examiner so suggest, the elements of the claims that are absent in the May reference as described above.

Accordingly, there is nothing in either the Sun or May references when combined which would lead one skilled in the art to come up with the present invention in which there is direct contact of the sample portion of an immunoassay test strip that is exposed underneath the opening in the test card designed to receive the sample. Thus, rather than attacking the references individually, Applicants have shown that no cited reference, either individually or when combined, would lead one skilled in the art to the precise features of the invention as presently claimed, and thus the Examiner's

rejections on the basis of the combination of May and Sun are clearly traversed and should be withdrawn.

The last reference cited by the Examiner, the Boger US patent 4,518,565, also does not disclose the present invention, namely a test card which includes an immunoassay test strip and which has an opening through which the exposed sample receiving portion of the test strip is directly contacted by the liquid test sample so that the sample will travel up the strip to a test portion via capillary action. Indeed, once again, the Examiner used the Boger reference for the point that a casing/holder would have "ridges or other means which facilitate the preferred parallel alignment of the strips, because one would have had ample motivation to select from known and conventional alternative casing/holder components, such as the ridges defining slots to facilitate parallel test strip arrangement, with the expectation that such a known casing/holder design would perform its casing/holder and arrangement function." See Official Action of June 20, 2005. There was thus no disclosure in Boger which related whatsoever to the invention of the present claims, namely a test card which includes an immunoassay test strip and which has an opening through which the exposed sample receiving portion of the test strip is directly contacted by the liquid test sample so that the sample will travel up the strip to a test portion via capillary action, and thus once again the Examiner cannot combine Boger with any of the other cited references in order to lead one skilled in the art to come up with the presently claimed invention. To the contrary, Boger relates to a chemical reagent pad and has nothing to do with a lateral flow immunoassay test which is the subject of the present invention. Accordingly, Boger cannot be added to the other references in any fashion to anticipate or make obvious Applicants' claimed invention.

Accordingly, the Examiner's rejections of the claims on the basis of the cited prior art references, insofar as applied to the claims as amended, are respectfully traversed and should be withdrawn.

Finally, the Examiner rejected Claims 16-19 on the basis of obviousness-type double patenting over claims 1-7 of US Patent No. 6,372,515, and without addressing the merits of this rejection, the rejection is respectfully traversed by the filing of a Terminal Disclaimer herewith.

In light of the amendments and arguments as set forth above, and the attachments hereto, Applicants respectfully submit the present application has been placed in condition for allowance, and such action is earnestly solicited.

END OF REMARKS